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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/687,384 | 10/13/2000 | Timothy G. Dinan | 99,829-A | 7338 |
| 7590 | 01/18/2005 | | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRNETT & DUNNER, L.L.P. 1300 I STREET, NW WASHINGTON, DC 20005-3315 | | | JAGOE, DONNA A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1614 | |

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------|-----------------|--------------|
| Advisory Action | Application No. | Applicant(s) |
| | 09/687,384 | DINAN ET AL. |
| | Examiner | Art Unit |
| | Donna Jagoe | 1614 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) The period for reply expires 6 months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on 28 September 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will not be entered because:
 - (a) they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) they raise the issue of new matter (see Note below);
 - (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. Applicant's reply has overcome the following rejection(s): _____.
4. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: see number 2.
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1 and 4-7.

Claim(s) withdrawn from consideration: _____.

8. The drawing correction filed on _____ is a) approved or b) disapproved by the Examiner.

9. Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

10. Other: _____.


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Continuation of 2. NOTE: Applicant asserts that since the prior art (Buzas) teaches that carbonic anhydrase inhibitors, when used in combination with certain other specified compounds, including some beta blockers like pindolol, provide a synergistic effect. In reply, the definition of synergy, obtained from <http://cancerweb.ncl.ac.uk/cgi-bin/omd?query=synergy&action=Search+OMD> is the interaction of two or more treatments such that their combined effect is greater than the sum of the individual effects observed when each treatment is administered alone. For this to be established, it would follow that the beta-adrenergic blocker, such as pindolol, administered alone is effective in treating gastrointestinal disease, and when combined with the carbonic anhydrase inhibitor, the net effect is greater than when one agent is administered alone. It would not be interpreted as either agent, when administered alone, would not treat gastrointestinal disease, rather, it means that each agent, administered alone can treat gastrointestinal disease, but when administered together, the net effect is greater. Again, by recitation of the transitional phrase, "consisting essentially of" if an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989 (see MPEP §2111.03). It does not appear that the addition of the carbonic anhydrase inhibitor of Buzas et al. would materially change the characteristics of the applicant's invention since both agents would treat gastrointestinal disease.